

REMARKS/ARGUMENTS

Reconsideration of the present application, as amended, is respectfully requested.

A. STATUS OF THE CLAIMS

As a result of the present amendment, claims 21, 31, 36 and 53-54 are presented in the case for continued prosecution.

Claim 21 has been amended to set forth more specifically what Applicants believe to be their invention. Support can be found, for example, in Examples in the application, such as Table 12 on page 73 of the amended specification, clean copy, filed on December 22, 2005.

Claims 22-29 have been previously canceled without prejudice.

Claim 30 has been newly canceled without prejudice.

Claim 31 has been amended to remove "heterodimer" and limit the claim scope to "homodimer."

Claims 32-34 have been previously canceled without prejudice.

Claim 35 has been newly cancelled without prejudice.

Claim 36 has been amended to depend from claim 21.

The previously withdrawn claims 37-38, 41-47 have been newly canceled without prejudice.

Claims 39-40, 48-52 and 55 have been newly canceled without prejudice.

No new matter has been added.

B. SUBSTITUTE SEQUENCE LISTING

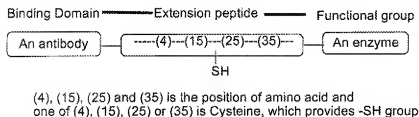
On page 2, the Examiner objected to the specification based on the newly added claim 52, which recites a polypeptide sequence without a SEQ ID NO. Claim 52 has been canceled and, thus, the objection is rendered moot.

Nevertheless, claim 21 as amended herein contains a peptide sequence for the extension peptide, (S/A)KPSI(S/A)T(K/Q)AS(G₄S)_nGGPE, and a substitute sequence listing has been submitted herewith.

No new matter has been added.

C. CLAIM OBJECTIONS

On page 3, claim 21 was objected for being allegedly lack of clarity in part (iii). Without admitting the appropriateness of the Examiner's position and for the purpose of facilitating prosecution, claim 21 has been amended to limit to contain one cysteine residue in the "extension peptide" located at 4th, 15th, 25th, or 35th position from the conjugated position to the binding domain in the extension peptide linker having a sequence represented by (S/A)KPSI(S/A)T(K/Q)AS(G₄S)_nGGPE, wherein (n) is an integer ranging from 0 to 8 and one of 4th, 15th, 25th or 35th amino acid is substituted with a cysteine. In other words, the extension peptide could have a sequence such as (S/A)KPC_I(S/A)T(K/Q)AS(G₄S)_nGGPE, (S/A)KPSI(S/A)T(K/Q)AS(G₄C)_nGGPE, etc. For the convenience of the Examiner's review, a schematic description of the construct in claim 21, as amended herein, is provided below. As amended herein, Applicants believes that the description is properly clear.



On page 3, claim 30 was objected for clerical errors. Claim 30 has been canceled and thus, rendering the objection moot.

On page 3, claim 52 was objected for allegedly containing a non-specified sequence. Claim 52 has been canceled and thus, rendering the objection moot.

As a result of the amendment and the reason above, thus, the Applicants respectfully request the objections being withdrawn.

D. CLAIM REJECTIONS UNDER 35 USC §112, FIRST PARAGRAPH

On pages 3-4, the Examiner rejected claims 21, 30, 31, 35, 36, 39, and 40 under 35 USC § 112, first paragraph as allegedly failing to meet the written description requirement. Even though the Examiner appreciated that the binding domain is now recited as an antibody, a ligand or a receptor in the Applicants' last amendment, the Examiner indicated that the antibody can still bind

to any antigen, not just a cell-surface antigen, and a ligand is a protein that binds to anything. The Examiner further indicated that binding domain need not be a protein.

Applicants respectfully disagree.

Applicants respectfully would like to draw the Examiner's attention that, as amended herein, claim 21 recites a recombinant fusion protein comprising a binding domain which is further specified as an antibody binding to a cell-surface antigen. As the Examiner indicated, a general binding domain need not be a protein. However, an antibody is well-understood and accepted by the skilled in the art as a polypeptide. Examples of antibody can be found, for example, in the Examples on pages 31 and the following pages.

On pages 4-8, the Examiner rejected all pending claims under 35 USC § 112, first paragraph as allegedly failing to meet the written description requirement. The Examiner noted that there are examples of three polypeptides in the application. In addition, the Examiner indicated that the claims only contain functional limitations such as homo- or hetero-multimerization, which do not define the structural features for the subject matter. The Examiner required (1) identifying characteristics of the claimed molecule; and (2) a representative number of species within the genus must be disclosed. In addition, on page 6, all pending claims are rejected under 35 USC § 112, first paragraph, allegedly failing to meet the enablement requirement. The Examiner indicated that the application only provides three homo-dimerization affinity domains. On page 7, the Examiner indicated that the specification does not support the broad scope of the claims encompassing homo- or hetero-multimerization, i.e. polypeptides having any length and structure.

Without admitting the appropriateness of the Examiner's position and for the purpose of facilitating prosecution, claim 21 has been amended to further limit the binding domain as an antibody and to remove recitation of "a ligand and a receptor", to limit the extension peptide having one uncoupled cysteine residue located at 4th, 15th, 25th, or 35th position from the conjugated position to the binding domain, and to limit the extension peptide having a sequence (S/A)KPSI(S/A)T(K/Q)AS(G₄S)_nGGPE, wherein (n) is an integer ranging from 0 to 8 and one of 4th, 15th, 25th or 35th amino acid is substituted with a cysteine. In addition, claim 31 has been amended to remove "heterodimer" to recite only "homodimer."

It is believed that the instant claims as amended herein meets the written description

requirement and defines the structural features for the subject matter claimed clearly.

As a result of the amendment and the reason above, thus, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 USC § 112, first paragraph.

E. CLAIM REJECTIONS UNDER 35 USC § 112, SECOND PARAGRAPH

On page 8, all pending claims are rejected under 35 USC § 112, second paragraph for allegedly being indefinite. The Examiner indicated that the descriptions in claims, for example, 21, 50, and 52 are not clear.

As amended herein, claim 21 recites a recombinant fusion protein monomer having a(i) an antibody; (ii) an enzyme; and (iii) an extension peptide having a sequence represented by (S/A)KPSI(S/A)T(K/Q)AS(G₄S)_nGGPE, wherein (n) is an integer ranging from 0 to 8 and one of 4th, 15th, 25th of 35th amino acid is substituted with a cysteine to form a disulfide bond for dimerization.

As a result of the amendment and the reason above, thus, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 USC § 112, second paragraph.

F. FEES

This response is being filed timely with a petition for three month extension and the required fee. In addition, a Request for Continued Examination and the required fee are submitted herewith. No further fee is believed to be required. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275.

Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

G. CONCLUSION


In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner have been addressed by the present

amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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